



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,079	07/02/2003	Ray C. Wasielewski	ORW01-GN003	5826

30074 7590 12/29/2006
TAFT, STETTINIUS & HOLLISTER LLP
SUITE 1800
425 WALNUT STREET
CINCINNATI, OH 45202-3957

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
----------	--------------

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/612,079	Applicant(s) WASIELEWSKI, RAY	
	Examiner Anu Ramana	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 77-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-76 and 105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 64, lines 2-3, the limitation, "one fastener for mounting the lining to at least one of the stabilizing post of the tibial component and the inner surface of the femoral component at least partially defining," renders the claim vague and indefinite since it is unclear whether the fastener is for mounting to the intercondylar channel or just an inner surface of the femoral component. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14, 17, 20, 41-54, 57 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferguson (US 6,592,622).

Ferguson discloses a band assembly or "prosthetic stabilizing device" 14 including a resorbable lining that is capable of being mounted to at least one of a tibial component 10 so that the lining is between the tibial component and a femoral component and approximate a prosthetic intercondylar channel (Figs. 1-4 and col. 5,

Art Unit: 3733

lines 1-59). Note that Ferguson discloses that the prosthesis assembly of his invention can be used with an implanted femoral component which would have an intercondylar channel to interact with bearing insert 32 (col. 9, lines 65-67 and col. 10, lines 1-2).

Claim 105 is rejected under 35 U.S.C. 102(b) as being anticipated by Engelbrecht et al. (US 4,790,853).

Engelbrecht et al. disclose a knee-joint prosthesis including a tibial component, a femoral component and a lining 40 positioned between the tibial and the femoral components (Figs. 1 and 2, col. 4, lines 36-56 and col. 6, lines 23-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 16, 18, 19, 21, 22, 33-40, 55, 56, 58, 59, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson (US 6,592,622) in view of Scarborough (US 6,616,698).

Ferguson discloses all elements of the claimed invention except for an antibiotic agent such as gentamicin, a clotting factor and osteogenic materials such as stem cells and transforming growth factor.

It is very well known to use gentamicin as an antibiotic and osteogenic materials such as stem cells and transforming growth factor in implants as evidenced by Scarborough (col. 6, lines 17-55).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an antibiotic such as gentamicin and osteogenic materials such as stem cells and transforming growth factor in the Ferguson

Art Unit: 3733

implant, since it was well known to use these materials for their intended purpose, namely, promoting bone growth and prevention of infection.

Claims 23-25 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson (US 6,592,622).

Ferguson discloses a first lining 36 constructed of a resorbable material and a second lining 34 constructed of an inert material. Ferguson also discloses that fasteners or sutures 38 can be used to bind the two linings together (col. 5, lines 1-44 and lines 60-67 and col. 6, lines 1-4).

Ferguson discloses all elements of the claimed invention except for band 34 being constructed of an inert material that is biologic in origin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed band 34 of an inert material that is biologic in origin, for e.g. collagen or ECM, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferguson (US 6,592,622) in view of Yencho et al. (US 6,461,320).

Ferguson discloses all elements of the claimed invention except for a fastener such as a clip.

Yencho teaches the equivalence of sutures and clips for the purpose of connecting two members (col. 4, lines 27-29).

It would have been obvious to one of ordinary skill in the art to substitute a clip as, for example, taught by the Yencho reference for the suture of the Ferguson device wherein so doing would amount to mere substitution of one functionally equivalent fastener for another within the same art and the selection of any of these fasteners would work equally well in the claimed device.

Claims 63 and 65-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helfet (RE 29,757) in view of Valentini (US 5,759,205).

Helfet discloses a knee joint prosthesis including a femoral component 16, a tibial component 17 and a lining mounted to a stabilizing post of the tibial component wherein the lining is made of a synthetic resin plastic material (Fig. 7, col. 3, lines 6-68 and col. 4, lines 1-30).

Helfet discloses all elements of the claimed invention except for the lining being made of a biologic material.

Valentini teaches natural and synthetic materials that are biocompatible and/or biodegradable (col. 6, lines 55-67 and col. 7, lines 1-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the synthetic resin material of Helfet with a biologic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein biocompatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on October 9, 2006 have been fully considered but are not persuasive for the following reasons.

Applicants' arguments with respect to the rejections of claims 1-3, 5-15, 17, 20, 23-25, 27-28, 29-34, 38, 41, 45-54, 57-58 and 60 under 35 USC 102(b) are moot in view of the new grounds of rejection.

Regarding the rejection of claims 63 and 65-76, as being obvious over Helfet (RE 29,757) in view of Valentini, it is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Helfet clearly shows a lining mounted to at least the stabilizing post of the a tibial component (Fig. 7). Further,

Art Unit: 3733

Valentini teaches the use of natural (biologic) and synthetic materials or combinations thereof that are biocompatible and/or biodegradable. The Examiner is relying on this teaching to demonstrate that one of ordinary skill in the art would consider substituting the synthetic resin liner of Helfet with a biologic biocompatible material, not biodegradable biocompatible material per Applicants' arguments. Applicants state that a biologic material may not be a biologically reabsorbable material (para [0036]).

Regarding the rejection of claim 105 as being anticipated by Engelbrecht et al., the Examiner notes that repositioning of the lining does not hinder the functionality of the femoral component and the tibial component.

Allowable Subject Matter

The allowability of claims 42-44 is being withdrawn in view of the new rejections made in this office action.

Claim 64 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

December 26, 2006

A handwritten signature in black ink, appearing to read "Anuradha Samara". The signature is written in a cursive, flowing style.